

WHAT IS CLAIMED IS:

1. An improved method for lyophilizing or freeze-drying a product, wherein the improvement comprises adding ascorbate to the product prior to lyophilizing or freeze-drying the product, the amount of said ascorbate added being effective to lower the residual solvent content of said product following lyophilization or freeze-drying.

2. The method according to claim 1, wherein the product has a residual solvent content of less than about 15% following said lyophilization or freeze-drying.

3. The method according to claim 1, wherein the product has a residual solvent content of less than about 10% following said lyophilization or freeze-drying.

4. The method according to claim 1, wherein the product has a residual solvent content of less than about 5% following said lyophilization or freeze-drying.

5. The method according to claim 1, wherein the product has a residual solvent content of less than about 3.0% following said lyophilization or freeze-drying.

6. The method according to claim 1, wherein the product has a residual solvent content of less than about 2.0% following said lyophilization or freeze-drying.

7. The method according to claim 1, wherein the product has a residual solvent content of less than about 1.0% following said lyophilization or freeze-drying.

8. The method according to claim 1, wherein the product has a residual solvent content of less than about 0.5% following said lyophilization or freeze-drying.

9. The method according to claim 1, wherein the product has a residual solvent content of less than about 0.2% following said lyophilization or freeze-drying.

10. The method according to claim 1, wherein the product has a residual solvent content of less than about 0.08% following said lyophilization or freeze-drying.

11. The method according to claim 1, wherein said ascorbate is sodium ascorbate.

12. The method according to claim 11, wherein said sodium ascorbate is present in an amount of at least about 100 mM.

13. The method according to claim 11, wherein said sodium ascorbate is present in an amount of from about 5 to about 500 mM.

14. The method according to claim 13, wherein said sodium ascorbate is present in an amount of from about 10 to about 400 mM.

15. The method according to claim 14, wherein said sodium ascorbate is present in an

amount of from about 50 to about 300 mM.

16. The method according to claim 15, wherein said sodium ascorbate is present in an amount of from about 75 to about 200 mM.

17. The method of claim 1, wherein the product comprises an enzyme.

18. The method of claim 17, wherein said enzyme is alpha-galactosidase.

19. The method according to claim 17, wherein said enzyme is trypsin.

20. The method according to claim 17, wherein said enzyme is iduronate-2-sulfatase.

21. The method according to claim 1, wherein said product is a blood component.

22. The method according to claim 21, wherein said blood component is a blood protein.

23. The method according to claim 22, wherein said blood protein is selected from the group consisting of albumin, lipoproteins, complement proteins, globulins, Factor I (fibrinogen), Factor II (prothrombin), Factor III (tissue factor), Factor V (proaccelerin), Factor VI (accelerin), Factor VII (proconvertin, serum prothrombin conversion), Factor VIII (antihemophiliac factor A), Factor IX (antihemophiliac factor B), Factor X (Stuart-Prower factor), Factor XI (plasma thromboplastin antecedent), Factor XII (Hageman factor), Factor XIII (protransglutamidase), von Willebrands factor (vWF), Factor Ia, Factor IIa, Factor IIIa, Factor Va, Factor VIa, Factor VIIa, Factor VIIIa, Factor IXa, Factor Xa, Factor XIa, Factor XIIa, Factor XIIIa, hemoglobin and growth factors.

24. The method according to claim 21, wherein said blood component is a liquid blood component.

25. The method according to claim 24, wherein said liquid blood component is plasma or serum.

26. The method according to claim 1, wherein said product is a proteinaceous material.

27. The method according to claim 1, wherein said product is an immunoglobulin.

28. The method according to claim 27, wherein said immunoglobulin is selected from the group consisting of polyclonal IgA, IgM, IgG and IgE and monoclonal immunoglobulin.

29. The method according to claim 1, wherein said product is a coagulation protein.

30. The method according to claim 29, wherein said coagulation protein is selected from the group consisting of Factor VII, Factor VIII, Factor IX and von Willebrands factor.

31. A product made according to the process of one of claims 1-30.

32. An improved method for lyophilizing or freeze-drying a product, wherein the improvement comprises adding a compound effective to reduce residual solvent content to the product prior to lyophilizing or freeze-drying the product, the amount of said compound added being effective to lower the residual solvent content of said product following lyophilization or freeze-drying.

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33. The method according to claim 32, wherein said compound effective to reduce residual solvent content is selected from the group consisting of mannitol, ascorbic acid, sodium ascorbate and methyl ascorbate.

34. The method according to claim 33, wherein said compound effective to reduce residual solvent content is mannitol.

35. The method according to claim 33, wherein said compound effective to reduce residual solvent content is sodium ascorbate.

36. The method according to claim 32, wherein the product has a residual solvent content of less than about 15% following said lyophilization or freeze-drying.

37. The method according to claim 32, wherein the product has a residual solvent content of less than about 10% following said lyophilization or freeze-drying.

38. The method according to claim 32, wherein the product has a residual solvent content of less than about 5% following said lyophilization or freeze-drying.

39. The method according to claim 32, wherein the product has a residual solvent content of less than about 3.0% following said lyophilization or freeze-drying.

40. The method according to claim 32, wherein the product has a residual solvent content of less than about 2.0% following said lyophilization or freeze-drying.

41. The method according to claim 32, wherein the product has a residual solvent content of less than about 1.0% following said lyophilization or freeze-drying.

42. The method according to claim 32, wherein the product has a residual solvent content of less than about 0.5% following said lyophilization or freeze-drying.

43. The method according to claim 32, wherein the product has a residual solvent content of less than about 0.2% following said lyophilization or freeze-drying.

44. The method according to claim 32, wherein the product has a residual solvent content of less than about 0.08% following said lyophilization or freeze-drying.

45. The method of claim 32, wherein the product comprises an enzyme.

46. The method of claim 45, wherein said enzyme is alpha-galactosidase.

47. The method according to claim 45, wherein said enzyme is trypsin.

48. The method according to claim 45, wherein said enzyme is iduronate-2-sulfatase.

49. The method according to claim 32, wherein said product is a blood component.

50. The method according to claim 49, wherein said blood component is a blood protein.

51. The method according to claim 50, wherein said blood protein is selected from the

group consisting of albumins, lipoproteins, complement proteins, globulins, Factor I (fibrinogen), Factor II (prothrombin), Factor III (tissue factor), Factor V (proaccelerin), Factor VI (accelerin), Factor VII (proconvertin, serum prothrombin conversion), Factor VIII (antihemophilic factor A), Factor IX (antihemophilic factor B), Factor X (Stuart-Prower factor), Factor XI (plasma thromboplastin antecedent), Factor XII (Hageman factor), Factor XIII (protransglutaminase), von Willebrands factor (vWF), Factor Ia, Factor IIa, Factor IIIa, Factor Va, Factor VIa, Factor VIIa, Factor VIIIa, Factor IXa, Factor Xa, Factor XIa, Factor XIIa, Factor XIIIa, hemoglobin and growth factors.

52. The method according to claim 49, wherein said blood component is a liquid blood component.
53. The method according to claim 52, wherein said liquid blood component is plasma or serum.
54. The method according to claim 32, wherein said product is a proteinaceous material.
55. The method according to claim 32, wherein said product is an immunoglobulin.
56. The method according to claim 55, wherein said immunoglobulin is selected from the group consisting of IgA, IgM, IgG and IgE and monoclonal immunoglobulins.
57. The method according to claim 32, wherein said product is a coagulation protein.
58. The method according to claim 57, wherein said coagulation protein is selected from the group consisting of Factor VII, Factor VIII, Factor IX and von Willebrands factor.
59. The method according to claim 32, wherein said compound effective to reduce residual solvent content comprises mannitol and sodium ascorbate.
60. A product made according to the process of one of claims 32-59.
61. A method for prophylaxis or treatment of a disease or infection in a mammal comprising administering to a mammal in need thereof an effective amount of a product made according to the method of one of claims 1-30.
62. The method according to claim 61, wherein said mammal is a human.
63. A method for prophylaxis or treatment of a disease or infection in a mammal comprising administering to a mammal in need thereof an effective amount of a product made according to the method of one of claims 32-59.
64. The method according to claim 63, wherein said mammal is a human.
65. The method according to one of claims 1-30 and 32-59, wherein said solvent is water.